OCT 1 9 2000

K000730

510(k) Summary

SUBMITTED ON BEHALF OF:

	Company Name:	**ImpoAID, Inc.**
	Address:	**401 Ocean Bluffs Blvd, Unit 505**
		Jupiter, FL 33477
	Telephone:	**561-747-8588**
	Fax:	**561-747-8588**
by:		Elaine Duncan, MS.ME., RAC
		President, Paladin Medical®, Inc.
		PO Box 560
		Stillwater, MN 55082
Telephone:		715-549-6035
Fax:		715-549-5380

CONTACT PERSON: **Elaine Duncan**

DATE PREPARED: **March 1 , 2000**

TRADE NAME: **ImpoAID**
COMMON NAME: **External Penile Rigidity Ring**

SUBSTANTIALLY EQUIVALENT TO:
The ImpoAID is similar in design and features to devices described in K974082, K974173, and K844445. There are no substantial differences that could present a risk to safety.

DESCRIPTION of the DEVICE:
The **ImpoAID** is a male impotency aid device for enabling a man to acquire and maintain an erect penis. Device is sized to fit snugly on the penis without strangulation and has a notch to align with the penile urinary tract and which has a rim that extends outward from the device for positioning. The fitting kit contains 16 ring sizes and 1 tube of lubricating jelly.

INDICATIONS FOR USE:
The ImpoAID is an external penile rigidity ring for male impotency. It is sold in various sizes designed to closely conform to individual requirements. The rings are placed around the base of the penis to help sustain an erection. The rings operate by limiting venous return from the major superficial veins of the penis.

SUMMARY of TESTING:
Biocompatibility and extensive history of the Tecoflex shows the material to be safe for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 9 2000

ImpoAID, Inc.
c/o Elaine Duncan, M.S.M.E., RAC
President, Paladin Medical, Inc.
P.O. Box 560
Stillwater MN 55082-0560

Re: K000730
ImpoAID, Inc. External Penile Rigidity Device
Dated: July 31, 2000
Received: August 3, 2000
Unclassified/Procode: 78 LKY

Dear Ms. Duncan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known) K000730

Device Name: ImpoAID External Male Impotence Ring

Indications for Use:

The ImpoAID is an external penile rigidity ring for male impotency. It is sold in various sizes designed to closely conform to individual requirements. The rings are placed around the base of the penis to help sustain an erection. The rings operate by limiting venous return from the major superficial veins of the penis.

(Please Do Not Write Below This Line-Continue On Another Page If Needed)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over -The-Counter Use ✓

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000730